**REMARKS**

Applicants filed a Request for Continued Examination and the requisite fee on May 31, 2005 requesting entry of the March 29, 2005 amendment. Accordingly, claims 55-67 are now pending in the instant application. In the Advisory Action dated April 12, 2005, the Examiner acknowledged these claims to overcome the rejection under 35 U.S.C. 102 over Chang and the rejection under 35 U.S.C. 112, second paragraph. However, the Examiner suggested that claim 63 raised issues of new matter in that it no longer required a secretion signal. Further, the Examiner maintained the rejection under 35 U.S.C. 112, first paragraph for lack of enablement.

By this Preliminary Amendment Applicants have amended claims 55, 58, 60, 61, 63 and 66 and canceled claims 57, 59 and 67 in light of these amendments. Applicants have added new claims 68 through 73 which are supported by the originally filed claims. No new matter is added by these amendments and entry is respectfully requested.

Applicants respectfully disagree with the Examiner's suggestion that claim 63 no longer requires a secretion signal. This claim specifically states that the non-infectious eukaryotic expression vector nucleic acid construct comprises a secretion signal of rainbow trout

transforming growth factor (TGF-beta). Thus, no new matter was added in claim 63.

Applicants also respectfully disagree with the Examiner's maintaining the enablement rejection.

The Examiner suggests that teachings of Tjelle et al. (2004) do not overcome the enablement rejection because the work is limited to intramuscular injection of plasmid DNA; the immunization is limited in the time frame; and the discussion concerning the potential use of the described concept in humans is speculative rather than conclusive ("may" is used rather then "will"). A similar issue regarding Perez not stating that that data is "reasonably predictive" is raised by the Examiner.

It is respectfully pointed out, however, that almost all immunizations are limited in the time frame. Claims of the instant application are not drawn to providing life-long immunity (at least without repeated treatment).

Further, as honest researchers, Tjelle et al. and Perez do not make conclusions about the effect in humans, since they have made no trials with humans. However, the fact that the concept works not only in fish, but also in as different animals as mice and sheep, highly supports the assumption that it will be widely applicable throughout the

animal kingdom including in humans. Clinical trials with humans will be needed to confirm efficacy, but that is a general point for all types of medical methods/ pharmaceuticals, and clinical trial data is normally not required to obtain a patent in the medical field.

With respect to the Examiner's questioning the relevance of Zon (1999), this reference was not cited as being enabling for immunizations, but rather to demonstrate that disease models in fish looked promising for prediction of results in humans, already at the time of filing of the application and that one trained in the art therefore would consider fish as suitable animal models of human diseases. This has later been confirmed in a number of other studies.

However, in an earnest effort to advance the prosecution of this case, Applicants have amended the claims to be drawn to the animal model (fish) and type of disease-causing agent (virus) specifically used in the provided proof of concept experiments. Further, in light of the Examiner's comments with respect to teachings of Tjelle et al. relating to plasmid versus nucleic acid construct, Applicants have amended the claims to be drawn to plasmids. Support for this amendment is provided in the specification at page 3, lines 28-31.

These claims are clearly enabled by the instant specification and withdrawal of all rejection under 35 U.S.C. 112, first paragraph is respectfully requested.

Finally, Applicants respectfully disagree with the Examiner that Applicants arguments against Duan as prior art are contradictive and that Duan teaches an "improvement over the prior art thereby recognizing the prior art actually uses such signal sequences". This might be the case in terms of use of secretion signal in cell culture experiments as conducted by Duan. However, there is a significant difference between protection of a single cell as described by Duan and protecting a whole animal organism, as claimed in the instant invention. For protection of single cells in vitro Duan´s concept of using an antibody gene not encoding a secretion signal might have an advantage. However, no in vivo experiments are conducted by Duan, and in order to apply the principle of Duan in an animal, all cells of the animal susceptible to virus infection would have to express the recombinant antibody. With today's knowledge and available technologies, this is not possible with a non-infectious antibody gene construct. Duan does not consider the use of non-infectious antibody gene constructs with secretion signal as a realistic approach for establishment

of protection of an animal, but this is contradicted by the present invention as well as by later work such as that of Perez and Tjelle. Thus, Applicants maintain that the work of Duan should not be considered as relevant prior art in relation to the present invention.

**Conclusion**

Applicants believe that the foregoing comprises a full and complete response to the Advisory Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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